

**This Page Is Inserted by IFW Operations
and is not a part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- **BLACK BORDERS**
- **TEXT CUT OFF AT TOP, BOTTOM OR SIDES**
- **FADED TEXT**
- **ILLEGIBLE TEXT**
- **SKEWED/SLANTED IMAGES**
- **COLORED PHOTOS**
- **BLACK OR VERY BLACK AND WHITE DARK PHOTOS**
- **GRAY SCALE DOCUMENTS**

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

THIS PAGE BLANK (USPTO)

12

EUROPEAN PATENT APPLICATION

21 Application number: 79301837.5

51 Int. Cl.³: A 61 M 25/02

22 Date of filing: 06.09.79

30 Priority: 06.09.78 GB 3584478

43 Date of publication of application:
16.04.80 Bulletin 80/8

84 Designated Contracting States:
AT BE CH DE FR GB IT LU NL SE

71 Applicant: Peters, Joseph Lennox
282B Ballard Lane
Finchley London N.12(GB)

71 Applicant: Wilson, Richard Ylverton
Ashlands Church Walk
Ulverton Lancashire(GB)

71 Applicant: Ashford, Colin John
9 Pickley Wood Hayes
Bromley Kent(GB)

72 Inventor: Peters, Joseph Lennox
282B Ballard Lane
Finchley London N.12(GB)

74 Representative: Simpson, Ronald Duncan Innes et al,
A.A.Thornton & Co. Northumberland House 303-306
High Holborn
London WC1V 7LE(GB)

54 Surgical safety device and method of securing a body tube.

57 A surgical safety device to be fixed externally to the body of a patient fitted with a body tube for securing the body tube against unintentional displacement into or out of the patient, comprises a bore (3,5) for receiving the tube, an element (6) for gripping the tube, and means (1,2) for selectively adjusting the element (6) between a tube gripping position and a tube released position. As shown, two tubular members (1,2) are partially telescoped together and the gripping element (6) has its opposite ends (7,8) fast with the respective members for strips (11) of the element to be wound spirally around the tube in response to relative rotation of the tubular members (1,2). A ratchet system (12,13) serves to lock the members (1,2) in the tube gripping position.

A method of securing a surgical body tube is characterised by the steps of passing the body tube through the bore (3,5) of the safety device, adjusting the safety device to grip securely the body tube without collapsing it, and fixing the safety device to the external body surface of the patient.

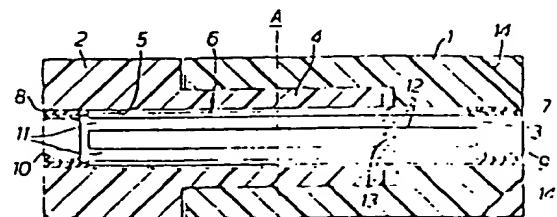


FIG. 2.

TITLE MODIFIED

see front page

- 1 -

SURGICAL SAFETY DEVICE

This invention is concerned with surgical equipment and methods used in hospitals. More particularly the invention relates to a safety device for use with body tubes and to a method of securing a body tube using a safety device.

In the treatment of patients it is not uncommon for tubes to be inserted into the body of a patient, either through an existing body orifice or an opening specially provided. Such tubes are referred to generally as body tubes and specific examples of such tubes include catheters or cannulae used for blood or other administration purposes, drainage tubing introduced into body cavities, especially after operations, for draining off fluids, and naso-gastric tubes. It is normal practice for body tubes to be secured to the patients skin outside of the body in order to avoid any inadvertant displacement of the tube either into or out of the body. Such securement is, in some cases, achieved simply by means of a strip of adhesive tape whereas in other cases a bandage may be used.

It is especially important that drainage tubes, for example inserted through wounds into thoraxis or abdominal cavities, should be securely held against unintentional movement either into the body or out of it. Different techniques have been used for this purpose and include stitching the tubing to the skin of the patient at a location where it emerges through the wound, wrapping a thread stitched to the patient around the

tubing several times to grip and hold the tubing, and attaching a safety pin to the patients skin by loops of thread and then pushing the safety pin laterally through the tube wall. These known methods have several disadvantages, but the main drawback is that adjustments of the surgical drains, for example by shortening the length of tube located within the body, are difficult and time consuming because of the manipulations required, and as a result can be painful to the patient. The fact that there is not a standard technique used by all surgeons who instead are guided by personal preferences does not ease the tasks of nurses who have to perform adjustments later.

The present invention aims at providing a solution to the problems associated with securing body tubes and broadly resides in a tubular device, to be fixed externally to the body of a patient fitted with a body tube, the body tube passing through the device which is adjustable either to grip the tube securely or to release the tube to allow the tube to be pulled freely through the device.

The adjustment of the device may be a simple operation, for example relative rotation or axial movement of two tubular parts making up the device, which, when the device is fitted to a drainage tube for example, facilitates any necessary re-positioning of the tube which is achieved simply by adjusting the device to release the tube, pulling the tube through the device to the new position, and retightening the device.

Drainage tubes are normally flexible and made of plastics material or rubber, especially silicone rubber, with the consequence that they can be easily crushed or pinched to close the central passageway.

A preferred form of device according to the invention is suitable for use with such tubes and is

- 3 -

constructed so as to avoid the device exerting too strong
a ^{constricting or} clamping action on the tube while still gripping the
tube securely enough to prevent any movement of the tube
through the device. To be more specific the device
5 comprises two relatively rotatable tubular members tele-
scoped one inside the other, and an elongate flexible
element positioned within the tubular/and having its
opposite ends fast for rotation with the respective
members. When the members are rotated with respect to
10 each other the elongate element wraps itself onto a tube
passing through the device and securely holds the tube.
Means, preferably in the form of a ratchet, are provided
for locking the members releasably in their adjusted
angular positions with respect to each other.

15 The device can, of course, take other forms and
in a particularly simple construction comprises two
tubular parts screw threaded together and adjustable
relative to each other to deform a tube gripping element
interposed between them radially inwards for gripping a
20 tube.

Another form of device which is envisaged con-
sists of a first tubular part having a plurality of
axially extending integral fingers adapted to be deflected
inwardly by a second part to grip a tube passed through
25 the device. The second part is preferably adjustable
between several positions so as to deflect the fingers
by varying amounts for gripping different diameter tubes.

The invention also resides in a method of secur-
ing a surgical body tube externally of a patient compris-
30 ing the steps of providing a tubular safety device capable
of adjustment either to grip frictionally or to release a
tube passed through the device, passing the tube through
the safety device, attaching the device to the body of
the patient, and adjusting the device to grip securely
35 the tube without collapsing the tube and closing its

- 4 -

interior passage.

One particular form of safety device embodying the invention will now be described by way of example with reference to the accompanying drawing, in which:-

- 5 Figure 1 is a side view of the device;
 Figure 2 is an axial section through the device;
 Figure 3 is a transverse cross-section taken
 along the line A-A in Figure 2; and
 Figure 4 is the same section as Figure 3, but
10 showing the device adjusted to grip
 a tube.

The safety device illustrated in the drawings is tubular and includes front and rear main parts 1 and 2, respectively, which are cylindrical and coaxial. The
15 front part 1 has an axial bore 3 and a counterbore into which a forwardly protruding boss 4 of the rear part extends. The rear part 2 has an axial bore 5 which aligns with the bore 3 of part 1 and an elongate gripping element 6 of flexible and slightly elastic material is accommodat-
20 ed within the bores 3,5. The element 6 has tubular end portions 7,8 which are fixed firmly to the opposed ends of parts 1,2 by force-fitted sleeves 9,10 which clamp the end portions against the walls of bores 3,5. The end portions of the gripping element are interconnected by
25 a plurality, four as shown, of integral strips 11. Thus the gripping element has the form of a tube with four longitudinal slots cut in its wall.

The internal shoulder formed in front part 1 and the forward end of the boss 4 are provided with ratchet
30 teeth 12,13 which cooperate to permit relative rotation between the front and rear parts 1,2 in one direction only. At its forward end the front part 1 is provided with holes 14 for thread 15 by means of which the device can be attached to the body of a patient.

35 In use of the device, with the device adjusted

as seen in Figures 2 and 3, the body tube, for example surgical drainage tube T, to be secured is passed through the device. The forward end of the device is then attached to the patients body by thread 15 passing through holes 14 and stitched to the skin. The device is adjusted to grip firmly the tube T by relatively rotating the front and rear parts 1,2 in the direction permitted by the ratchet teeth 12,13. Because the ends of the gripping element 6 are fast with the respective parts 1,2, the relative rotation between them causes the element to twist so that the strips 11 tend to wind up to extend along generally helical paths and move inwardly to grip the tube T (Figure 4). The strips 11 engage the tube over a substantial length, for example approximately 4 cms, which means that the tube can be held firmly without being crushed or pinched closed. When the device has been tightened the correct amount, the ratchet teeth 12,13 prevent it loosening.

If, subsequently, it is desired to adjust the position of the tube, such as to shorten the drain, to release the tube the front and rear parts 1,2 are pulled axially apart to disengage the ratchet teeth 12,13 and are then turned to loosen the gripping element 6. The tube T can be pulled easily through the device for adjusting its position, after which the device can be tightened again, as described above, to secure the tube once more.

It is to be noted that as the strips 11 are twisted they tend to draw together axially the parts 1,2 bringing the ratchet teeth into tighter engagement and thereby making the device more secure against inadvertent loosening of the tube. Of course, means other than the ratchet teeth could be provided for locking the two parts 1,2 in their adjusted positions.

The described safety device can be used with

-6-

tubes of different diameters and the two parts 1,2 could be provided with registration marks which would indicate at a glance when the device had been adjusted correctly for each tube diameter. Alternatively the device could be intended for use with one size tube only and be provided with means to limit positively the permitted rotation between parts 1 and 2.

The front and rear parts of the device are conveniently moulded from plastics material and, if required either or both, could be provided with means to assist attachment of the device to a patient, for example a flange plate which could be held in place on the body by a strip of adhesive tape.

Alternatively or additionally a groove could be provided around the periphery of the device for receiving a strap, such as a velcro strap, to be wrapped around a limb of the patient for attaching the device thereto.

The inner gripping element 6 of the inventive device has been described and illustrated as having its ends fastened to the main, outer ports 7,2 by force fitted sleeves. However, it will be recognised that other means could be used. For example, the element could be provided with external flanges at its ends which are received in shallow counterbores in the outer ends of the parts 1,2 and have a splined connection with the ports 1,2 making its opposite ends fast with the respective parts. The splines could conveniently be formed on the flangers.

Other modifications to the illustrated safety device and alternative forms of device will occur to those readers skilled in the art.

CLAIMS

1. A surgical safety device to be fixed externally to the body of a patient fitted with a body tube (T), characterised by a through bore (3,5) for receiving the body tube (T), a gripping element (6) for gripping the body tube (T) received in the bore, and means (1,2) selectively operable to adjust the gripping element (6) between a first position in which the body tube (T) is firmly gripped and held against longitudinal movement through the safety device to prevent unintentional displacement of the body tube into or out of the patient, and a second position in which the body tube (T) is released by the gripping element (6) to allow the body tube (T) to be pulled freely through the safety device.

2. A safety device as claimed in claim 1, for use with a body tube having a flexible wall, wherein the gripping element (6) is adapted to engage the body tube (T) over an extended longitudinal portion thereof so as to grip the body tube securely without collapsing the body tube.

3. A safety device according to claim 1 or 2, wherein the said adjusting means comprises a pair of tubular members (1,2) telescoped together to define the through bore (3,5) and movable relative to each other, the gripping element (6) being adjustable between the first and second positions by relatively moving the tubular members in a predetermined manner.

- 8 -

4. A safety device as claimed in claim 3, wherein the tubular members (1,2) are rotatable relative to each other about the axis of the through bore (3,5) for adjusting the gripping element (6).

5. A safety device as claimed in claim 4, wherein the gripping element (6) is elongated and flexible, and has its opposite ends (7,8) fast for rotation with the respective tubular members (1,2),

6. A safety device as claimed in claim 5, wherein the gripping element (6) includes a plurality of strip (11) spaced apart around the periphery of the bore (3,5) and integrally attached to each other at the ends (7,8) of the gripping element, the strips (11) extending longitudinally of the bore in the second position and spirally about the bore axis and the body tube (T) in the first position.

7. A safety device according to claim 4, 5 or 6, including locking means (12,13) normally permitting relative rotation of the tubular members (1,2) in one direction only, which direction is in the sense to tighten the grip on the body tube, the locking means (12,13) being releasable to permit relative rotation of the tubular members (1,2) to release the body tube (T).

8. A safety device according to claim 7, wherein the locking means comprises a ratchet system including cooperating teeth (12,13) on the tubular members (1,2).

- 9 -

9. A safety device according to claim 8 wherein the cooperating ratchet teeth (12,13) are axially opposed and are disengageable by pulling the tubular members apart axially.

10. A method of securing a surgical body tube fitted to a patient externally of the patient, characterised by the steps of providing a tubular safety device having a through bore (3,5) capable of receiving the body tube and selectively adjustable to grip frictionally the body tube received in the bore or to release the body tube, passing the body tube through the bore (3,5) of the safety device, adjusting the safety device to grip securely the body tube without collapsing the body tube and closing its interior passage, and fixing the safety device to the external body surface of the patient.

1/1

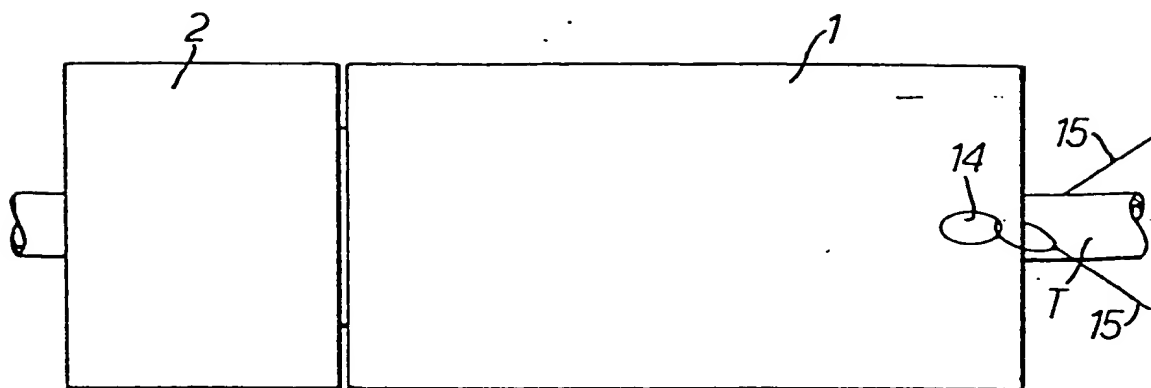


FIG. 1.

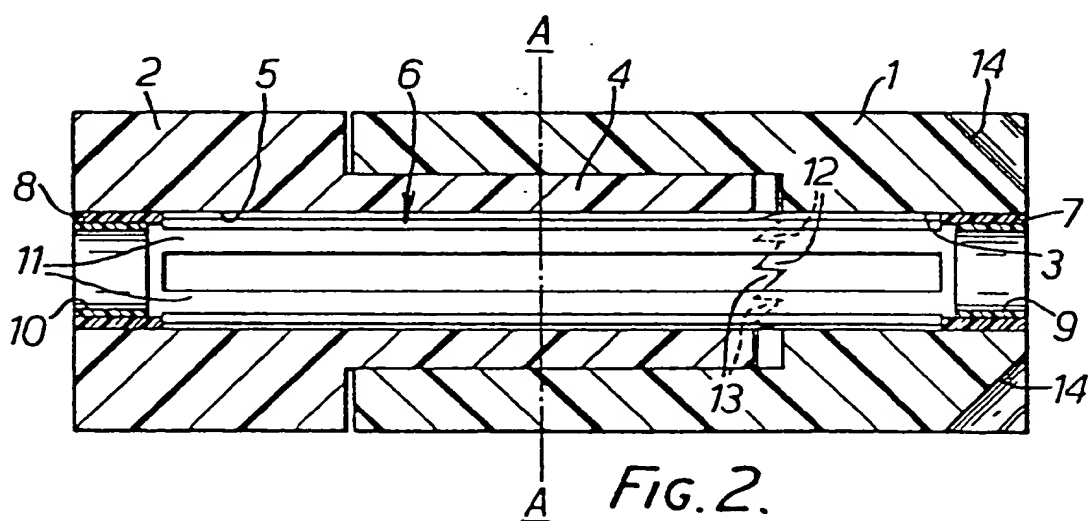


FIG. 2.

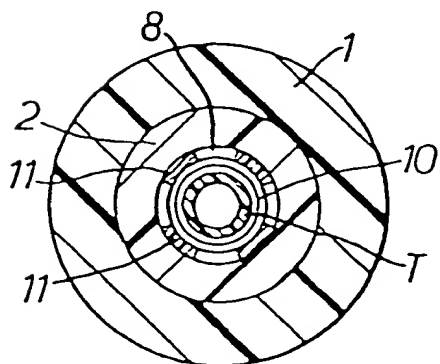


FIG. 3.

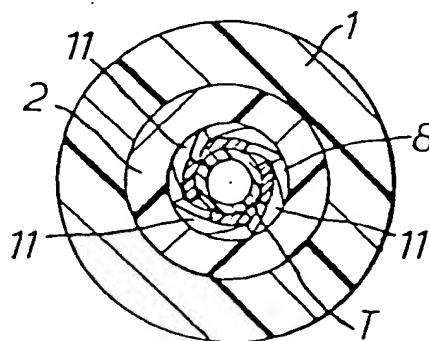


FIG. 4.



EUROPEAN SEARCH REPORT

0009893

Application number

EP 79 301 837.5

EPO Form 1503.1 06.78